ACUTE DERMAL IRRITATION STUDY OF
IN
ALBINO RABBITS

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This summary of data and conclusions is based upon the sample received. Additional studies may be required as specific uses and formulations are developed or if process changes occur.

ABSTRACT

An acute dermal irritation study was designed to determine the skin irritation potential of to the skin of rabbits. The procedure followed was in accordance with the acute dermal irritation studies specified in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981. A single semi-occluded contact of 0.5 ml with the intact skin of six male albino rabbits for four hours did not result in any observable irritation or swelling when examined at 1, 24, 48, or 72 hours after washing. On the basis of the data presented in this report, it is concluded that is a non-irritant to the skin of rabbits. It is unlikely that any problems of skin irritation will result from a single, short-term skin contact with this material in its industrial use.

*Amine siloxane hydrolyzate

Distribution

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TEST MATERIAL

A clear, colorless liquid identified as was submitted to the Toxicology Department for the determination of dermal irritation potential and an assessment of the industrial handling hazards associated with acute exposure. The procedure for testing this material was based on methods recommended in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981.

METHOD

Six young male albino rabbits of the New Zealand white strain (obtained from Langshaw Farms, Augusta, Michigan) were employed in this study. Animals were kept in quarantine for seven days prior to initiation of the study and only suitable animals were used for the experiment. All rabbits were housed individually in clean, stainless steel cages in a temperature, humidity and light controlled room. The animals were maintained on a standard PURINA® Rabbit Chow and fresh water ad libitum. Each rabbit was identified by an individual permanent ear tag.

Twenty-four hours prior to dermal application, the hair of each rabbit was closely clipped from the dorsal body surface area of the trunk with electric clippers.

A single dose of 0.5 ml test material was uniformly applied to one intact test site (approximately 6 cm^2) of each animal. Adjacent areas of untreated skin served as control. The application site was covered with a porous gauze dressing and the animal was then wrapped in a semiocclusive fashion with a cotton cloth bandage taped to the hair. After a four hour exposure period, the bandages were removed and the skins were washed with tap water. Animals were observed frequently after dosing and twice a day thereafter, up to 72 hours following the exposure for signs of toxicity and behavioral abnormalities. The degree of skin irritation was scored according to Table I at 60 minutes, 24, 48, and 72 hours after washing for erythema, edema, and other evidence of irritation or injury.

RESULTS

Table II presents the skin irritation scores with time. A single semi-occlusive contact of 0.5 ml of with intact skin for four hours did not result in any observable effect in any of the rabbits when examined at 1, 24, 48, or 72 hours after washing. No abnormalities in test animal behavior were noted and no obvious effects on body weight or food consumption were observed during the study.

CONCLUSIONS

Under the conditions of this test, a four hour semi-occluded skin contact with 0.5 ml did not result in any observable irritation to the skin of rabbits and is therefore considered as a non-irritant. A single, short-term skin contact with this material may not cause any problems of skin irritation during its industrial handling.

REFERENCES

"O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981.

This Report constituted of pages 1-6, and Tables I & II, signed this 9th day of April, 1985.

Authors:

Approved By: _____

Toxicology Department

Typed By:

QUALITY ASSURANCE STATEMENT

This report represents data generated by the Toxicology Department, This study was conducted according to the EPA Toxic Substances Control; Good Laboratory Practices Regulations; 40 CFR, Part 797, Vol. 48, No. 230. The results of the report accurately reflect the data generated. All raw data is located at

Study Started:	February 12, 1985
Study Completed:	February 15, 1985
Date Audited:	February 12, 1985 and February 15, 1985
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April 9, 1985
Date:

TABLE I

EVALUATION OF SKIN REACTION

	Value
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 milliliter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4
Severe eschar and/or corrosion	Note Occurence

TABLE II

Mean Skin Irritation Scores of
in Male Rabbits

Parameter	Mean Score Reading Interval (Time Post Wash) 60 Min.	24 Hrs.	48 Hrs.	72 Hrs.
Erythema & Eschar:	0	0	0	0
Edema Formation:	0	0	0	0
Total Scores:	0	0	0	0
Primary Irritation Scores:	0/8	0/8	0/8	0/8